PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

**William R. Campbell, et al.**

Serial No.: 09/483,084

Filed: 14 January 2000

For: **FORMULATIONS AND METHODS FOR ADMINISTRATION OF PHARMACOLOGICALLY OR BIOLOGICALLY ACTIVE COMPOUNDS**

Group Art Unit: Not Assigned

Examiner: Not Assigned

Atty. Dkt. No.: 00981-0007-US00

**PETITION UNDER 37 C.F.R. §1.182 IN SUPPORT OF SUBMISSION OF OMITTED PAGE 4 TO PATENT APPLICATION ACCORDED EARLIER FILING DATE**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The specification for the above-captioned application was filed on January 14, 2000, as Application Serial No. 09/483,084. No amendments have been submitted and no Office Actions on the merits have been received. Applicant's attorney received a "Notice to File Missing Parts of Nonprovisional Application - Filed Under 37 CFR §1.53(b) - Filing Date Granted" on March 28, 2000, which was mailed on March 22, 2000. The Notice indicated that page 4 of the specification (description and claims) appears to have been omitted from the application. Upon inspection of the file in the PTO it appears that the document "misfed" through the photocopier in such a manner that part of page 4 was not copied and submitted with the application as filed.

Regrettably, this error was not noticed when the application was filed. A copy of page 4 is attached hereto for convenience.

This petition is pursuant to 37 CFR §1.182 where "all situations not specifically provided for in the regulations of this part will be decided in accordance with the merits of each situation by or under the authority of the Commissioner, subject to such other requirements as may be imposed,....." By this petition, applicant seeks the following relief. The entire, above-captioned application should get a filing date of January 14, 2000, because as shown herein, page 4 does not contain matter which is not repeated elsewhere in the specification as filed and received by the PTO. Alternatively, all of the pages except page 4 should be given the January 14, 2000 filing date, and page 4 should be given a filing date of the when the supplemental declaration was signed by the joint inventor, **WILLIAM R. CAMPBELL,** namely May 19, 2000.

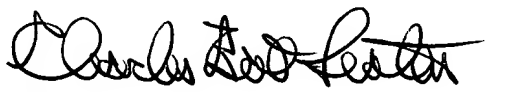
All matter appearing on page 4 appears elsewhere in the specification (description and claims). Page 4 contains a partial summary of what is frequently termed the "objects of the invention." This is an overview of concepts appearing later in the application. Specifically, from page 4, the disclosure appearing in lines 1-3, is also found in line 1-2 of the Abstract (page 25) of the original application, and line 13 of page 8. Furthermore, the disclosure in the complete sentence appearing on lines 3-5 of page 4, also appears in part in lines 6-8 of the original Abstract (page 25), and lines 5-8 of the original "Field of Invention" (page 1). Still further, the disclosure of "methods of the present invention" in lines 6-14 of page 4, also appears in lines 11-16 of the original Abstract (page 25), and lines 21-22 of the original "Summary of the Invention" (page 2). Even still further, the disclosure of "In a preferred embodiment ..." in lines 15-17 of page 4, also appears in lines 7-9 of the original "Field of Invention" (page 1). Finally and still further, the disclosure that begins with "However, the person of ordinary skill in the art ...." in

lines 18-23 of page 4, also appears in lines 3-12 of page 11, line 17 of page 5 ("wide range of .... compounds"), and line 7 of page 7 ("diluted in an aqueous solution") of the specification.

Alternatively, it would be unfair under these circumstances to accord the entire application the filing date of May 19, 2000 should the PTO decide that page 4 is denied the January 14, 2000 filing date. In such a case, that page alone should be given the May 19, 2000 filing date. There is no legitimate basis to deny the January 14, 2000 filing date to the pages which were properly filed. If this petition is denied, applicants reserve the right to delete page 4 from this application. Accordingly, the entire specification, including page 4 is entitled to the filing date of January 14, 2000. Pursuant to 37 CFR §1.182, "any petition seeking a decision under this section must be accompanied by the petition fee set forth in §1.17(h). The Assistant Commissioner therefore is hereby authorized to deduct the appropriate fee from Deposit Account 08-3038 .

Respectfully submitted,

Dated: 22 May 2000



Charles Bret Seaton
Reg. No. 46,171

HOWREY SIMON ARNOLD & WHITE
Box 34
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2402
(858) 622-5100

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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**William R. Campbell, et al.**

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Filed: 14 January 2000

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Group Art Unit: Not Assigned

Examiner: Not Assigned

Atty. Dkt. No.: 00981-0007-US00

#3

**PETITION UNDER 37 C.F.R. § 1.47(b) FOR ACCEPTANCE OF APPLICATION WHERE JOINT INVENTOR HAS REFUSED TO SIGN THE DECLARATION**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The specification for the above-captioned application was filed on January 14, 2000, as Application Serial No. 09/483,084. No amendments have been submitted and no Office Actions on the merits have been received. Applicant's attorney received a "Notice to File Missing Parts of Nonprovisional Application - Filed Under 37 CFR 1.53(b) - Filing Date Granted" on March 28, 2000, which was mailed on March 22, 2000.

This petition is made to set forth the facts relied upon to establish the diligent effort made to secure the execution of the declaration by the hostile, non-signing, joint inventor for the above-identified patent application after deposit thereof in the Patent and Trademark Office ("the Office"), and to request the Office to accept the application under these

circumstances. Because signing on behalf of the non-signing joint inventor is by the other joint inventor or entity showing a sufficient proprietary interest, this statement also recites facts as to why this action was necessary to preserve the rights of the parties or to prevent irreparable damage.

Extensive efforts were made prior to filing this application and have been made since the filing of this application to obtain the signature of hostile, non-signing joint inventor, **BARRY A. OMILINSKY ("Omilinsky").** The details of efforts to obtain the signature of the hostile joint inventor are set forth in the accompanying declaration of Mary S. Consalvi and the accompanying statement/declaration William R. Campbell filed herewith. The last known addresses of Omilinsky is shown below:

(1) The co- inventor, **OMILINSKY** of the above-captioned application is an independent contractor hired by **BLUE RIDGE PHARMACEUTICALS, INC.** (hereinafter "**BLUE RIDGE**") specifically to work on the subject matter of this invention. A copy of the agreement between **OMILINSKY** and **BLUE RIDGE** (with confidential financial items redacted) is attached to the Statement/Declaration of William R. Campbell filed herewith. At the time the invention was conceived, and at all subsequent times, **BLUE RIDGE** was and is the owner of all of the rights in and to this application because **OMILINSKY** has signed both an agreement obligating him to assign this invention to **BLUE RIDGE**, as well as an Assignment of Patent Application to **BLUE RIDGE**. *See* Statement Establishing Proprietary Interest by Person Signing on Behalf of Non-signing Inventor, filed herewith, ¶ 4. By virtue of this Agreement, **BLUE RIDGE** is a juristic entity having sufficient proprietary interest in this application to act on **OMILINSKY's** behalf.

(2) **OMILINSKY** was generally cooperative during the preparation of the application. He provided a thorough initial disclosure to the patent attorney drafting the application. *See* Declaration of Mary S. Consalvi in Support of Petition Under 37 C.F.R. § 1.47(b) for Acceptance of Application Where Hostile Co-Inventor Has Refused to Sign the Declaration, filed herewith, ¶ 2 (hereinafter, the "Consalvi Declaration"). Thereafter, **OMILINSKY** significantly participated in preparing the application. However, after the Application was filed, when **OMILINSKY** was requested to sign the Combined declaration of inventorship and power of attorney presented to him, he refused to sign it.

(3) Communications to **OMILINSKY** were made to his home telephone number which he had previously provided to **BLUE RIDGE**. The address and telephone number provided to **BLUE RIDGE** at that time and to which these communications were directed were:

24 Landing Lane
Princeton, NJ 08550
USA
Home Phone: (609) 799-5641

(4) Since **OMILINSKY** has refused and continues to refuse to sign the Inventor's Declaration, the other joint inventor and **BLUE RIDGE** employee, **WILLIAM R. CAMPBELL** ("Campbell"), has made the declaration on **OMILINSKY's** behalf. Mr. Campbell has also signed the Declaration in Support of a Filing Date for Omitted Page 4 of the Application. Mr. Campbell worked on this project with **OMILINSKY** and was responsible for hiring **OMILINSKY** onto the project, and so is intimately familiar with the invention and the facts surrounding **OMILINSKY'S** refusal to sign. *See* Campbell Decl., ¶ 4.

(5) The application was filed on January 14, 2000. The undersigned received the "Notice to File Missing Parts of Nonprovisional Application - Filed Under 37 CFR 1.53(b) - Filing Date Granted" on or about March 27, 2000. *See* Consalvi Decl., ¶ 5. **OMILINSKY** was first asked to sign a combined declaration and power of attorney and assignment for this application on or about March 6, 2000. At or about that date a combined declaration and power of attorney which had already been signed by co-inventor Campbell was forwarded to him for signature. Omilinsky refused to sign and return the documents. After his initial refusal, we obtained a copy of the agreement between Omilinsky and Blue Ridge to confirm his obligations under it. In a subsequent conversation with Omilinsky we reminded him of his obligations. *See* Consalvi Decl., ¶ 3. This conversation apparently caused him to sign and return the assignment document, but he maintained his refusal to sign the combined declaration and power of attorney. Given his refusal we nevertheless requested him to send back the combined declaration and power of attorney which already had been signed by co-inventor Campbell. He refused. *See* Consalvi Decl., ¶ 4. Given his refusals we drafted a second combined declaration and power of attorney and forwarded it to co-inventor Campbell for re-signature. Consalvi Decl. ¶ 5.

*****

Because joint inventor **BARRY A. OMILINSKY**, has refused to sign the inventor's declaration, **BLUE RIDGE PHARMACEUTICAL, INC.**. hereby petitions pursuant to 37 C.F.R. § 1.47(b) that this application be accepted and granted a filing date of January 14, 2000. With regard to page 4 of the specification which the Office contends is missing from the PTO file, **BLUE RIDGE** hereby petitions that this page be given a filing date no later

than the filing date of the supplemental declaration relating to page 4. This action is necessary to prevent the loss of patent rights. The last known address of **OMILINSKY** is:

24 Landing Lane
Princeton, NJ 08550
USA
Home Phone (609) 799-5641

No fee is believed to be due in connection with the filing of this document. However, should any fee under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to this document, the Assistant Commissioner is hereby authorized to charge Howrey Simon Arnold & White's Deposit Account No. 08-3038.

Respectfully submitted,

Dated: May 22, 2000

Charles B. Seaton
Reg. No. 46,171 for
Mary S. Consalvi
Reg. No. 32,212

Howrey Simon Arnold & White, LLP
Box 34
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(858) 622-5100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

**William R. Campbell, et al.**

Serial No.: 09/483,084

Filed: 14 January 2000

For: **FORMULATIONS AND METHODS FOR ADMINISTRATION OF PHARMACOLOGICALLY OR BIOLOGICALLY ACTIVE COMPOUNDS**

Group Art Unit: Not Assigned

Examiner: Not Assigned

Atty. Dkt. No.: 00981-0007-US00

**DECLARATION OF PATENT ATTORNEY MARY S. CONSALVI IN SUPPORT OF PETITION UNDER 37 C.F.R. § 1.47(b) FOR ACCEPTANCE OF APPLICATION WHERE JOINT INVENTOR HAS REFUSED TO SIGN THE DECLARATION**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

1. I am the attorney primarily responsible for patent prosecution matters for Blue Ridge Pharmaceuticals. Inc. (hereinafter "Blue Ridge"). My responsibilities include preparing and prosecuting the above-captioned application and supervising other attorneys and agents who work or have worked on this application.

2. One of the co-inventors, Dr. Barry A. Omilinsky (hereinafter "Omilinsky") was generally cooperative during the preparation of the application.

3. The application was filed on January 14, 2000. After the application was filed, we prepared an assignment document and a combined declaration of inventorship and power of attorney for the case. These documents were sent first to co-inventor William R. Campbell. Omilinsky was first asked to sign an assignment and combined declaration of inventorship and

power of attorney for this case on or about March 6, 2000, when he received the documents which already had been signed by co-inventor Campbell. Omilinsky immediately refused to sign the documents. After his initial refusal, I contacted our client to obtain a copy of the agreement between Omilinsky and Blue Ridge to confirm his obligations under the agreement. After this information was received, we had a second conversation with Omilinsky to remind him of his obligations and to request him to reconsider his position. His obligations under the ¶3.4 of the Agreement between Blue Ridge and Omilinsky (a copy of which is attached to the Declaration of William Campbell as Exhibit A filed herewith) are:

> During the period of Consultant's engagement by the Company and at all times thereafter, Consultant shall promptly execute any and all declarations, assignments, applications and other instruments which the Company shall deem necessary to apply for and obtain patent and copyright registrations in any country or otherwise to protect the Company's interests in the Intellectual Property.

4. Despite our efforts, Omilinsky maintained his refusal to sign the combined declaration and power of attorney, but he did sign and return the assignment document. We asked him to return the combined declaration and power of attorney which had already been signed by co-inventor Campbell, but he refused.

5. We received the "Notice to File Missing Parts of Application - Filing Date Granted" on or about March 27 2000. At this time, we also prepared papers to address the problem of the alleged omission of page 4 to the application as filed. As of May 18, 2000, Omilinsky was still refusing to sign the Declaration. Given the May 22, 2000 deadline for complying with the Notice to File Missing Parts of Application, applicants had no choice but to proceed with this petition.

6. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: May 22, 2000

MARY S. CONSALVI
Reg. No. 32,212

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

**William R. Campbell, et al.**

Appl. No.: 09/483,084

Filed: January 14, 2000

For: **FORMULATIONS AND METHODS FOR ADMINISTRATION OF PHARMACOLOGICALY OR BIOLOGICALLY ACTIVE COMPOUNDS**

Art Unit: 1614

Examiner: not yet assigned

Atty. Docket: 00981-0007-US00

**STATEMENT ESTABLISHING PROPRIETARY INTEREST BY PERSON SIGNING ON BEHALF OF NON-SIGNING INVENTOR**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

1. I, William R. Campbell, residing at 4849 Harvey Rd., Jamestown, North Carolina, 27282, am the person making the declaration on my behalf and on behalf of the non-singing inventor, Barry A. Omilinsky ("Omilinsky") as required by 37 C.F.R. §1.64. I make this declaration in support of the originally filed application, which I am informed and believe is entitled to a filing date of January 14, 2000, as well as with respect to page 4 of that application. With respect to page 4, I am informed and believe that the Patent Office has sent a "Notice to File Missing Parts of Nonprovisional Application," alleging that page 4 of the specification was not present in the specification as originally filed. With respect to page 4, I have made a Supplemental Declaration on my behalf and on behalf of the non-signing inventor Omilinsky to

support a filing date for page 4, which is no later than the date on which this Supplemental Declaration was made, i.e., May 19, 2000.

2. For reasons stated above, I am making this declaration in support of the

PETITION UNDER 37 C.F.R. § 1.47(b) FOR
ACCEPTANCE OF APPLICATION WHERE INVENTOR REFUSES
TO SIGN AFTER DILIGENT EFFORT

and in support of the

PETITION UNDER 37 C.F.R. § 1.182 IN SURPPORT OF
SUBMISSION OF OMITTED PAGE 4 TO PATENT APPLICATION
ACCORDED EARLIER FILING DATE

for the above-captioned application.

3. I have also read the above-identified specification and claims. I am a co-inventor with Omilinsky on this application.

4. I confirm that I have first hand knowledge that together with me the omitted inventor made the above-identified invention while obligated to assign this invention to my employer, Blue Ridge Pharmaceuticals, Inc. ("Blue Ridge"). Blue Ridge has a proprietary interest in this application by virtue of the Agreement dated May 5, 1999, between Omilinsky and Blue Ridge (Exhibit A hereto)(financial terms redacted) and the Assignment executed by Omilinsky on May 12, 2000 (Exhibit B hereto). I am an employee of Blue Ridge, the Assignee of this application. I hired Omilinsky, as an individual and as sole proprietor of his company, Ocapco, LLC, pursuant to Exhibit A to assist in the development of the subject matter of this invention. Pursuant to ¶2.1 he is obligated to assign this invention to Blue Ridge. He has done so as shown in Exhibit B. My first hand knowledge of Omilinsky's inventive contribution to this invention arises from my work with him, pursuant to this Agreement and my work in the preparation and prosecution of this application on behalf of Blue Ridge.

5. As of the date I signed the "Combined Declaration and Power of Attorney for Patent Application" for this application, and the "Supplemental Combined Declaration And Power Of Attorney In Supported Of Omitted Page Four For Patent Application Which Has Been Accorded Earlier Filing Date", the proprietary interest in this invention belonged to my employer, Blue Ridge Pharmaceuticals, Inc., 4249-105 Piedmont Parkway, Greensboro, North Carolina, 27410, and I am authorized to sign the statement on behalf of the Blue Ridge, my title being Director.

6. In accordance with 37 C.F.R. § 3.73, I hereby state that the evidentiary documents with respect to Blue Ridge Pharmaceuticals, Inc.'s ownership have been reviewed and that, to the best of my knowledge and belief, equitable title is in the assignee seeking to take this action.

Date: May 19, 2000

William R. Campbell
Director

# AGREEMENT

**THIS AGREEMENT** ("Agreement") is made and entered into as of the 13th day of May, 1999 (the "Effective Date") by and between **Ocapco, LLC**, a New Jersey corporation having its principal place of business at P.O. Box 2327 Princeton, NJ, 08543-2327 ("Consultant") and Blue Ridge Pharmaceuticals, Inc., a Delaware corporation having its principal place of business at 4249-105 Piedmont Parkway, Greensboro, North Carolina 27410 ("Company").

**WHEREAS,** the Company desires to engage Consultant to perform certain duties and to create certain proprietary formulations for the Company, pursuant to the terms and conditions of this Agreement; and

**WHEREAS,** Consultant desires to accept such engagement.

**NOW, THEREFORE,** in consideration of the foregoing premises and for other good and valuable consideration, the receipt and sufficiency of which Consultant hereby acknowledges, the parties agree as follows:

1. **DEFINITIONS.** The following terms, when used in this Agreement with initial capital letters, shall have the respective meanings set forth in this Article 1.

1.1 **Confidential Information.** The term "Confidential Information" shall mean all information (whether or not specifically labeled or identified as confidential), in any form or medium, that is disclosed to Consultant in the performance of duties for the Company and that relates to the development, manufacture, marketing or sale of the Product (as defined below) and any other information disclosed to Consultant by the Company that is identified in writing as confidential no later than 30 days after its oral or written disclosure to Consultant.

Confidential Information shall not include any information that: (a) has been publicly known through no wrongful act or breach of obligation of confidentiality; (b) was lawfully known to Consultant prior to the time it was disclosed to, or learned by, Consultant during Consultant's engagement by the Company; (c) was received by Consultant from a third party without a breach of any obligation of confidentiality by such third party; or (d) constitutes general skill and experience that Consultant acquired prior to, or acquires after, Consultant's engagement by the Company.

1.2 **Intellectual Property.** The term "Intellectual Property" shall mean any idea, invention, design, development, device, formulation, method or process (whether or not patented or patentable, reduced to practice or included in the Confidential Information) and all patents and patent applications related thereto, all copyrightable works and mask works (whether or not included in the Confidential Information), all registrations and applications for registration related thereto, and all Confidential Information.

1.3 **Net Sales.** The term "Net Sales" means gross sales of the Product by the Company or any of its Affiliates or licensees to unaffiliated third parties, less (a) discounts and allowances taken, (b) returns, (c) taxes and duties (other than taxes on the income of the Company or its Affiliates) and (d) shipping, insurance and similar expenses.

1.4 **Affiliate.** The term "Affiliate" means any entity controlling, controlled by or under common control with the Company.

## 2. CONSULTANT'S DUTIES AND COMPENSATION.

2.1 **Engagement.** The Company hereby engages the Consultant to provide the Company with a formulation that the Consultant has developed (the "Formulation") for a water-dilutable 2% Ivermectin product (the "Product") for use as a nematocide with but not limited to poultry, swine, sheep, cattle, horses, and companion animals. Consultant covenants and agrees that the Formulation was developed solely by its President Barry Omilinsky. Mr. Omilinsky has entered into an employment agreement with Consultant, including an obligation by Mr. Omilinsky to assign to Consultant any inventions and intellectual property rights arising from his work on behalf of Consultant. Neither Consultant nor Mr. Omilinsky shall be deemed to be an employee of the Company.

2.2 **No Subcontracting.** Consultant shall not subcontract any portion of Consultant's duties under this Agreement without the prior written consent of the Company.

2.3 **Payments.**

[REDACTED]

2.4 **Royalties.**

[REDACTED]

2.5 **Expense Reimbursement.** The Company shall reimburse the Consultant for all expenses reasonably incurred by Consultant in connection with the engagement contemplated hereby (the "Engagement"); provided, however, that Consultant shall not incur more than $500 per month of expenses without prior written authorization from the Company. These expenses are over and above all other payments.

## 3. OWNERSHIP OF INTELLECTUAL PROPERTY.

3.1 **Ownership.**

(a) All Intellectual Property related to the Engagement contributed to, or conceived or made by, Consultant or any employee or agent of Consultant during Consultant's engagement by the Company, including the Formulation, is, shall be and shall remain the exclusive property of the

Company. Consultant hereby assigns to the Company all right, title and interest in and to such Intellectual Property. The Company shall own all rights in all copyrightable works prepared by Consultant in the performance of the consulting activities under this Agreement. All such copyrightable works, including, but not limited to, all computer programs and documentation applicable thereto, shall be considered "works-made-for-hire" and shall be owned by the Company irrespective of any copyright notices or confidentiality legends to the contrary which may have been placed on such works by Consultant or by others. All copyright notices and confidentiality legends on all such copyrightable works authored by Consultant shall conform to the Company's practices and shall specify the Company as the owner of the work.

(b) The Company hereby grants to the Consultant an exclusive, worldwide, royalty-free license to use the Formulation and all Intellectual Property described in paragraph (a) above for [redacted] applications.

3.2 **Assignment after Termination.** Consultant acknowledges and agrees that any Intellectual Property specifically related to the Engagement contributed to, or conceived or made by, Consultant or any employee or agent of Consultant within twenty- four (24) months after termination of Consultant's engagement by the Company may have been conceived or made in significant part during, or as a result of, Consultant's engagement by the Company. Accordingly, Consultant agrees that such Intellectual Property will be presumed to have been conceived or made during the period of Consultant's engagement by the Company, unless and until established to the contrary by Consultant, and the Consultant hereby assigns such Intellectual Property to the Company.

3.3 **Keep Records.** Consultant shall keep and maintain adequate and current written records of all Intellectual Property in the form of notes, sketches, drawings, computer files, reports or other documents relating thereto. Such records will be and will remain the exclusive property of the Company and will be available to the Company at all times. The Company shall also maintain records of Net Sales and make these books and records available upon reasonable advance notice by the Consultant. Any inspection of these books and records by Consultant shall be during normal business hours and may be conducted no more than once in any six-month period.

3.4 **Further Assurances.** During the period of Consultant's engagement by the Company and at all times thereafter, Consultant shall promptly execute any and all declarations, assignments, applications and other instruments which the Company shall deem necessary to apply for and obtain patents and copyright registrations in any country or otherwise to protect the Company's interests in the Intellectual Property.

3.5 **Reversion of Rights to Consultant.** Notwithstanding anything in this Agreement to the contrary, in the event the Company and its licensees elect to discontinue sales of the Product within twenty-four (24) months after the Company commences commercial sale of the Product (whether or not such Product has been approved by the FDA), the Company shall reassign to Consultant all rights in and to the Formulation and the Intellectual Property related to the Product.

4. **NON-DISCLOSURE AND NON-USE.**

4.1 **Non-Disclosure.** Consultant acknowledges and agrees that Consultant shall have access and contribute to information and materials of a highly sensitive nature (including Confidential Information) and that a purpose of this Agreement is to protect the legitimate business interests of the Company therein. Consultant agrees that during the period of Consultant's engagement by the Company and three (3) years thereafter, unless Consultant first secures the written consent of the Company, Consultant shall not use for Consultant or anyone else, and shall not disclose to others, any Confidential Information, except to the extent such use or disclosure is required in the performance of Consultant's assigned duties for the Company or by law or court order. Consultant further agrees to use Consultant's best efforts and utmost diligence to safeguard the Confidential Information and to protect it against disclosure, misuse, espionage, loss and theft.

4.2 **Required Disclosures.** In the event that Consultant is required by law or court order to disclose any Confidential Information, Consultant: (a) shall notify the Company in writing as soon as possible, but in no event later than five (5) business days prior to any such disclosure; (b) shall cooperate with the Company to preserve the confidentiality of such Confidential Information consistent with applicable law; and (c) shall use Consultant's best efforts to limit any such disclosure to the minimum disclosure necessary to comply with such law or court order.

5. **TERM; TERMINATION.**

5.1 **Term and Termination.** The term of this Agreement shall commence on the Effective Date and shall continue thereafter until terminated (a) by the Company upon giving Consultant sixty (60) days prior written notice in the event the Company determines in its reasonable business judgment to discontinue its efforts to seek regulatory approval for and/or commercialize the Product, or (b) by either party in the event of material breach by the other party which is not cured within sixty (60) days of receiving written notice of such breach from the nonbreaching party.

5.2 **Return of Materials.** Upon the termination of Consultant's engagement by the Company for any reason, or at any time requested, Consultant shall promptly deliver to the Company all Confidential Information and Intellectual Property in Consultant's possession and control, and all copies thereof, in whatever form or medium, including, without limitation, written records, optical and magnetic media, and all other materials containing any Confidential Information or Intellectual Property. If the Company requests, Consultant shall provide written confirmation that Consultant has returned all such materials.

6. **REPRESENTATIONS AND WARRANTIES.** Consultant represents and warrants that: (a) Consultant has the full power and authority necessary to enter into this Agreement; (b) Consultant will not breach or violate any other agreement to which Consultant is a party by entering into this Agreement; and (c) all Intellectual Property contributed to, or conceived or made by Consultant, including the Formulation, will not to the best of Consultant's knowledge, infringe, misappropriate or include intellectual property of a third party.

## 7. GENERAL.

7.1 **Relationship of Parties.** Except as specifically provided herein, neither party shall act or represent or hold itself out as having authority to act as an agent or partner of the other party, or in any way bind or commit the other party to any obligations. Any such act will create a separate liability in the party so acting to any and all third parties affected thereby. The rights, duties, obligations and liabilities of the parties shall be several and not joint or collective, and nothing contained in this Agreement shall be construed as creating a partnership, joint venture, agency, trust or other association of any kind, each party being individually responsible only for its obligations as set forth in this Agreement.

7.2 **Transferability.** Consultant shall not assign, transfer or encumber this Agreement or any of its rights, duties or obligations hereunder, by operation of law or otherwise, without the prior written consent of the Company. The Company reserves the right, however, to assign this Agreement, provided that within 15 days after the assignment by the Company of its rights or obligations hereunder to any party other than an Affiliate, the Company shall pay the Consultant $20,000. It shall be a condition to any assignment by the Company of its rights and obligations hereunder that the assignee agree to be bound by all of the terms hereof, including without limitation, the Company's obligations to pay royalties to the Consultant under Section 2.4.

7.3 **Notices.** Any notices, consents or approvals required or permitted to be given hereunder shall be deemed to be given and sufficient when delivered in writing, first class United States certified or registered letter, return receipt requested, or by overnight delivery or courier service or by telecopy with written confirmation as set forth below.

To the Company:
Blue Ridge Pharmaceuticals, Inc.
4249–105 Piedmont Parkway
Greensboro, NC 27410
Attention: Roland Johnson
Facsimile: 336-852-4040
Telephone: 336-852-3540

With copy to:
General Counsel
IDEXX Laboratories, Inc.
One IDEXX Drive
Westbrook, ME 04092
Facsimile: 207-856-0347
Telephone: 207-856-0300

To Consultant:
**Ocapco, LLC**
P.O. Box 2327
Princeton, NJ, 08543-2327
Attention: Barry Omilinsky
Facsimile: 609-275-8242
Telephone: 609-275-8242

7.4 **Amendment.** This Agreement may only be amended by the parties by a subsequent written agreement executed by their duly authorized representatives.

7.5 **Waiver**. The waiver by the Company of any breach by Consultant of any provision hereof shall not be construed to be either a waiver of the provision itself, or of any succeeding breach of such provision or of any other provision hereof.

7.6 **Choice of Law**. This Agreement shall be governed by and construed in accordance with the domestic laws of the State of North Carolina, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of North Carolina or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of North Carolina. In furtherance of the foregoing, the internal law of the State of North Carolina shall control the interpretation and construction of this Agreement, even though under that jurisdiction's choice of law or conflict of law analysis, the substantive law of some other jurisdiction would ordinarily apply. Each party hereby submits itself to, and acknowledges the jurisdiction of, the courts of the State of North Carolina over any suit, action or other proceeding arising out of, or in connection with, this Agreement.

7.7 **Non-Compete**. Consultant acknowledges and agrees that, during Consultant's engagement by the Company, Consultant will be exposed to the Company's trade secrets regarding the Product. Therefore, during the term of this Agreement and for a period of one year after the termination of this Agreement for any reason, Consultant shall not without the prior written consent of the Company, directly or indirectly develop, manufacture, market or sell a water dilutable 2% Ivermectin product for use as a nematocide in poultry, swine, sheep, cattle, horses and companion animals.

7.8 **Acknowledgement of Reasonableness**. Consultant acknowledges and agrees that the limitations set forth in this Agreement are reasonable with respect to scope, duration, geographic area and otherwise, and are properly required to protect the legitimate business interests of the Company. In the event that any such limitation is found to be unreasonable by a court of competent jurisdiction, Consultant agrees that the maximum scope, duration, geographic area or other limitation as such court shall deem reasonable shall be substituted for the stated duration, scope, geographic area or other limitation. Furthermore, the provisions of this Agreement shall be severable, and if any provision of this Agreement is held or declared to be illegal, invalid or unenforceable, the remaining provisions of this Agreement shall not be affected and shall continue in full force and effect.

7.9 **Remedies**. Consultant acknowledges and agrees that Consultant's failure to comply with any of the terms and conditions of this Agreement shall irreparably harm the Company and that money damages would not adequately compensate the Company for such harm in the event of such non-compliance. Therefore, Consultant acknowledges and agrees that, in addition to any other remedies the Company may have, the Company shall be entitled to obtain a court order in any court of competent jurisdiction against acts of non-compliance by Consultant of this Agreement, without the posting of a bond or other security.

7.10 **Survival**. Sections 1.1, 1.2, 3.1, 3.2, 3.4, 4.1, 4.2, 5.2, 6, 7 and 8 shall survive the termination of this Agreement for any reason.

7.11 **Entire Agreement**. This Agreement and all Exhibits attached hereto and incorporated herein by this reference contain the entire agreement between the parties hereto with respect to the subject matter hereof and supersede any previous understandings or agreements, whether written or oral, in respect of such subject matter.

8. **ACKNOWLEDGEMENT.** Consultant acknowledges and agrees that Consultant has fully read and understands this Agreement, has had the opportunity to discuss this Agreement with Consultant's attorney, has had any questions regarding its effect or the meaning of its terms answered to Consultant's satisfaction, and, intending to be legally bound hereby, has freely and voluntarily executed this Agreement.

**IN WITNESS WHEREOF,** the parties have caused this Agreement to be executed by their duly authorized representatives as of this 5th day of May, 1999.

**OCAPCO, LLC**

By: _____

Name: Berry Ovitinsky

Title: President

**BLUE RIDGE PHARMACEUTICALS, INC.**

By: _____

Name: Stephen A. Capps

Title: Vice President

Patent
00981-0007-US00

# ASSIGNMENT OF PATENT APPLICATION

WHEREAS, I, **BARRY A. OMILINSKY**, a citizen of the UNITED STATES, (hereinafter referred to as "ASSIGNOR"), have invented and own a certain invention entitled **FORMULATIONS AND METHODS FOR ADMINISTRATION OF PHARMACOLOGICALLY OR BIOLOGICALLY ACTIVE COMPOUNDS**, for which application for Letters Patent of the United States of America was filed on **January 14, 2000**; and

WHEREAS, **BLUE RIDGE PHARMACEUTICALS, INC.**, a corporation organized and existing under and by virtue of the laws of the State of Delaware and having its principal place of business at **4249-105 Piedmont Parkway, Greensboro, NC 27410** (hereinafter referred to as "ASSIGNEE"), is desirous of acquiring the exclusive right, title and interest in, to and under said invention and in, to and under any Patent or similar legal protection to be obtained therefor in the United States of America, its territorial possessions and in any and all countries foreign thereto.

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, ASSIGNOR hereby sells, assigns, transfers and sets over unto the said ASSIGNEE, its successors and assigns, the full and exclusive right, title and interest to said invention and to all Letters Patent or application or similar legal protection, not only in the United States and its territorial possessions, but in all countries foreign thereto to be obtained for said invention by said application, and to any continuation, division, renewal, substitute or reissue thereof or any legal equivalent thereof in the United States or a foreign country for the full term or terms for which the same may be granted, including all priority rights under the International Convention; and ASSIGNOR hereby authorizes and requests the Commissioner of Patents and Trademarks to issue said Letters Patent or any legal equivalent thereof to said ASSIGNEE, its successors and assigns, in accordance with this Assignment.

ASSIGNOR hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this Agreement;

ASSIGNOR further covenants that ASSIGNEE will, upon its request, be provided promptly with all pertinent facts and documents relating to said application, said invention and said Letters Patent and legal equivalents as may be known and accessible to ASSIGNOR and will testify as to the same in any interference or litigation related thereto and will promptly execute and deliver to ASSIGNEE or its legal representative any and all papers, instruments or affidavits required to apply for, obtain, maintain, issue and enforce said application, said invention and said Letters Patent and said equivalents in the United States or in any foreign country, which may be necessary or desirable to carry out the purposes thereof.

WITNESS my hand at Mercer County - New Jersey., _____, this 12th day of May., 2000.

BARRY A. OMILINSKY

STATE OF New Jersey )
) ss
COUNTY OF Mercer. )

On May 12-2000 before me, Eliana Soto., personally appeared **BARRY A. OMILINSKY**

☐ personally known to me - **OR** - ☒ proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

Eliana Soto.
Notary Public in and for said County and State

ELIANA SOTO
NOTARY PUBLIC STATE OF NEW JERSEY
MY COMMISSION EXPIRES NOVEMBER 23, 2004